Appendix D. Final Version of Scope

Domain	Key Question 1: Natural History	Key Questions 2 and 3: Speech/Language/Hearing	Key Question 4: Diagnostic Methods
Disease Entity	Type of OME (self-identified but note diagnostic method) • OME persisting after a discrete episode of AOM • Newly diagnosed OME of unknown duration • established OME persisting for weeks or months • unilateral OME lasting 3 months or longer • bilateral OME lasting 3 months or longer	All types of OME and unspecified OM that involve the presence of MEE. (At point of analysis, will stratify studies into those known for studying OME only, those unknown for studying OME or AOM, and those known for studying AOM specifically. The latter group will not be in the scope of this project.)	All types of OME (At the point of analysis, we will stratify studies that examine only diagnosis of MEE versus those that examine diagnosis of OME, i.e. MEE with absence of signs and symptoms).
Patient Population	Age at diagnosis: 0-12 years Age at followup: 0-12 years	Age at diagnosis: 0-3 years Age at followup: 0-9 years	Age: 0-12 years (In analysis, will stratify by age groups: 0-6, 6-36, and >36 months.)
Setting	Provider type: all Time period: 1966 forward Practice setting: all (Will stratify analysis by setting and time period, if possible.)	Provider type: all Time period: 1966 forward Practice setting: all (Will stratify analysis by setting and time period, if possible.)	Provider type: all Time period: 1966 forward Practice setting: all (Will stratify analysis by setting and time period, if possible.)
Exclusion factors	• Craniofacial defects such as cleft palate or aural atresia • Primary mucosal disorders such as immotile cilia syndromes or cystic fibrosis • Immunodeficiencies • Down syndrome or other genetically related syndrome • AOM Studies exclusively on children with the above conditions, either alone or combined, will not be included in the analysis. Studies that include children with and without the above conditions will	• Craniofacial defects such as cleft palate or aural atresia • Primary mucosal disorders such as immotile cilia syndromes or cystic fibrosis • Immunodeficiencies • Down syndrome or other genetically related syndrome • AOM Studies exclusively on children with the above conditions, either alone or combined, will not be included in the analysis. Studies that include children with and without the above conditions will	• Craniofacial defects such as cleft palate or aural atresia • Primary mucosal disorders such as immotile cilia syndromes or cystic fibrosis • Immunodeficiencies • Down syndrome or other genetically related syndrome • AOM Studies exclusively on children with the above conditions, either alone or combined, will not be included in the analysis. Studies that include children with and without the above conditions will

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Domain	Key Question 1: Natural History	Key Questions 2 and 3: Speech/Language/Hearing	Key Question 4: Diagnostic Methods
	be included if the data can be stratified by condition. If a study does not specify whether the above conditions are exclusion factors, it will be included in the analysis; and, a sensitivity analysis will be conducted on this study characteristic if possible.	be included if the data can be stratified by condition. If a study does not specify whether the above conditions are exclusion factors, it will be included in the analysis; and, a sensitivity analysis will be conducted on this study characteristic if possible.	be included if the data can be stratified by condition. If a study does not specify whether the above conditions are exclusion factors, it will be included in the analysis; and, a sensitivity analysis will be conducted on this study characteristic if possible.
Intervention	• Natural history • No treatment/no intervention/placebo	Any combination of the following: • No treatment • Tympanostomy tubes • Adenoidectomy • Myringotomy • Antibiotics • Systemic steroids • Decongestant • Antihistamine • Unknown (Will analyze by subgroups defined by multiple factors).	Not applicable
Diagnostic Methods	Not applicable	Not applicable	• Signs/symptoms • Non-pneumatic otoscopy • Pneumatic otoscopy, validated or un-validated examiner • Binocular micro-tympanoscopy • Portable tympanometer • Professional tympanometer • Quantitative tympanometry • Acoustic reflectometry (specify model and year) • Otoacoustic emissions • Audiometry, air or. bone conduction thresholds The above diagnostic methods may be in isolation or in combination with each other.

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Domain	Key Question 1: Natural History	Key Questions 2 and 3: Speech/Language/Hearing	Key Question 4: Diagnostic Methods
Gold Standard	Not applicable	Not applicable	One of the following: • Tympanocentesis, sedated or non-sedated • MRI • Myringotomy, sedated or non-sedated • Validated Pneumatic otoscopy • CT Scan
Non-treatment factors Influencing outcomes for Key Questions 1, 2, and 3 **OR** **Non-condition factors Influencing diagnostic performance for Key Question 4 (cont.)**	Demographic • age of child • gender • ethnicity/Race • socioeconomic status Environmental • number of hours attending child care center • tobacco smoke exposure • season of the year • number of children in household • not breast-fed • barotrauma challenges Symptoms/Signs • laterality, unilateral versus bilateral • hearing level, conductive or sensorineural Other clinical factors • total duration of OME (>=3 months) • age at first OM • age of onset of previous OME • number of previous OMEs • family history of OME • otitis prone (AOM) • allergies • prior tubes	Demographic • age at first OM • gender • ethnicity/race • socioeconomic status Environmental • number of hours attending child care center • quality of child care • tobacco smoke exposure • number of children in household • not breast-fed Symptoms/Signs • laterality, unilateral versus bilateral • hearing level, conductive or sensorineural Other clinical factors • total duration of OME (>=3 months) • number of previous OMEs • duration of MEE • repeated or persistent or infrequent early life OME • allergies • developmental delay Parent/caretaker • parent/caregiver education	Demographic • age of child Symptoms/Signs • laterality, unilateral versus bilateral Other clinical factors • age at first OM • anesthetic • developmental delay Examiner • Type of examiner (family physician, otolaryngologist, pediatrician, nurse practitioner, physician assistant, etc.)

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Domain	Key Question 1: Natural History	Key Questions 2 and 3: Speech/Language/Hearing	Key Question 4: Diagnostic Methods
	• prior adenoidectomy • developmental delay Parent/caretaker • parent/caregiver preference for treatment • parent/caregiver education Examiner • Skill to diagnose (validated examiner/observer) • Type of examiner (family physician, otolaryngologist, pediatrician, nurse practitioner, physician assistant, etc.) • Setting (Public, private, PPO, HMO, etc) Monitoring during episode or course of therapy • Monitoring time • Monitoring frequency • Monitoring personnel Type of monitoring method • tympanometry • acoustic reflectometry • ototscopy • pneumatic otoscopy • MRI	• quality of parent-child interaction Examiner • Skill to diagnose (validated examiner/observer) • Type of examiner (physician assistant, etc.) • Setting (Public, private, PPO, HMO, etc) Monitoring • Age at recheck • Frequency of recheck • Primary provider Equipment type • tympanometry • acoustic reflectometry • pneumatic otoscopy • MRI • equipment to measure auditory brainstem responses/brainstem auditory evoked responses • audiometry	
Outcome Measures	• Partial OME resolution (for bilateral OME only) • Complete OME resolution • AOM (The time or age at which each outcome was measured will be recorded)	• Long term hearing levels • Speech , expressive and receptive • Language, expressive and receptive • Cognition, measures of intelligence (verbal part of IQ test) (The time or age at which each outcome was measured will be recorded)	• Sensitivity • Specificity • Positive predictive value, and Prevalence rate • Negative predictive value, and Prevalence rate • Likelihood ratio

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Domain	Key Question 1: Natural History	Key Questions 2 and 3: Speech/Language/Hearing	Key Question 4: Diagnostic Methods
Literature Source	• MEDLINE • EMBASE • Cochrane Library • Proceedings of International OM Symposia • References from reference lists • References from Technical Expert Panel and Peer Reviewers and their publications	• MEDLINE • EMBASE • Cochrane Library • Proceedings of International OM Symposia • References from reference lists • References from Technical Expert Panel and Peer Reviewers and their publications	• MEDLINE • EMBASE • Cochrane Library • Proceedings of International OM Symposia • References from reference lists • References from Technical Expert Panel and Peer Reviewers and their publications
Language	English language exclusively. [Would attempt to review non-English literature if time permits].	English language exclusively. [Would attempt to review non-English literature if time permits].	English language exclusively. [Would attempt to review non-English literature if time permits].
Study Design	• natural history (observational) studies • Randomized Controlled Trials, blinded and unblinded • Non-randomized Controlled Trials, blinded and unblinded • Prospective/observational cohort studies	• Randomized Controlled Trials, blinded and unblinded • Non-randomized Controlled Trials, blinded and unblinded • Prospective cohort studies • Retrospective cohort studies	• Diagnostic studies/Cross-sectional studies
Wording of Key Questions	What is the natural history (spontaneous resolution rate over time without treatment) for: a) OME persisting after a discrete episode of acute otitis media b) Newly diagnosed OME of unknown duration (unilateral or bilateral) c) Established OME persisting for weeks or months (unilateral or bilateral) d) Unilateral OME lasting 3 months or longer e) Bilateral OME lasting 3	<u>Key Question 2</u>: Do children with OME with certain risk factor(s) have greater delays in their speech and language development (receptive or expressive) than those without those risk factor(s) or with other risk factor(s)? Specifically, the following subquestion will be investigated: a) Do infants and preschool children with repeated or persistent early life OME as compared to those with infrequent OME have greater	What are the sensitivity, specificity, and predictive values for the following alternative methods of diagnosing OME compared to one of the four gold standards? Alternative methods include: • Signs/symptoms • Non-pneumatic otoscopy • Pneumatic otoscopy, validated or un-validated examiner • Binocular micro-tympanoscopy • Portable tympanometer • Professional tympanometer • Quantitative tympanometry

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Domain	Key Question 1: Natural History	Key Questions 2 and 3: Speech/Language/Hearing	Key Question 4: Diagnostic Methods
	months or longer.	delays in the speech and language development (receptive or expressive) later in life? One specific formulation of this subquestion is: Is OME-associated conductive hearing loss in the first 3 years of life a risk factor for speech and language developmental delays? <u>Key Question 3</u>: Do children with OME with certain risk factor(s) have increased hearing loss (unilateral or bilateral) than those without those risk factor(s) or with other risk factor(s)? Specifically, the following subquestion will be investigated: a) Is OME-associated conductive hearing loss in the first 3 years of life a risk factor for permanent (or sensorineural) hearing loss later in life?	• Acoustic reflectometry (specify model and year) • Otoacoustic emissions • Audiometry, air or. bone conduction thresholds Gold standards include: • Tympanocentesis (sedated versus non-sedated) • MRI • Myringotomy (sedated versus non-sedated) • Validated pneumatic otoscopy • CT Scan
Key words for literature search	Two suggestions: a) Resolution and OM Duration of effusion b) Otitis media with effusion Mastoid	One suggestion: a) Otitis media with effusion Mastoid	Two suggestions: a) Otoscopy Pneumatic otoscopy Tympanometry Otoacoustic emissions b) Otitis media with effusion Mastoid